

U. S. PATENT AND TRADEMARK OFFICE  
U. S. DEPARTMENT OF COMMERCE

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

ATTORNEY'S SECRETARY NAME

21397P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**10/550136**

INTERNATIONAL APPLICATION NO.

PCT/US2004/015051

INTERNATIONAL FILING DATE

14 May 2004

PRIORITY DATE CLAIMED

19 May 1993

TITLE OF INVENTION

PROCESS FOR MAKING SPIROLACTONE COMPOUNDS

APPLICANT(S) FOR DO/EO/US

RALPH P. VOLANTE, STEVEN A. WEISSMAN, TAKEHIKO IIDA, YUHEI YAMAMOTO, HIROKI SATO, KENJI MAEDA, NAOTAKA SAWADA, and TOSHIAKI MASE

**Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:**

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures [35 U.S.C. 371(f)]. The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (PCT Article 31).
5. ☒ A copy of the International Application as filed [35 U.S.C. 371(c)(2)]
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed [35 U.S.C. 371(c)(2)].
  - a. ☐ is attached hereto
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 [35 U.S.C. 371(c)(3)].
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 [35 U.S.C. 371(c)(3)].
9. ☒ An oath or declaration of the inventor(s) [35 U.S.C. 371(c)(4)].
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 [35 U.S.C. 371(c)(5)].

**Items 11 to 20 below concern other document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

1005 Rec'd PCT/PTO 21 SEP 2005

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/550138</b>		INTERNATIONAL APPLICATION NO. PCT/US2004/015051		ATTORNEY'S DOCKET NUMBER 21397P	
The following fees are submitted:				<b>CALCULATIONS</b>	<b>PTO USE ONLY</b>
21. <input checked="" type="checkbox"/> Basic national fee.....\$300				\$300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0 All other situations.....\$200				\$0.00	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0 Search fee [37 CFR 1.445(a)(2)] has been paid on the international application to the USPTO as an International Searching Authority.....\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....\$400 All other situations.....\$500				\$0.00	
<b>TOTAL OF 21, 22 and 23=</b>				\$300.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
44 - 100 =	0 /50	0 = 0	X \$250.00	\$0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date [37 CFR 1.492(e)].					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	34 - 20 =	14	X \$50.00	\$700.00	
Independent Claims	2 - 3 =	0	X \$200.00	\$0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00		
<b>TOTAL OF ABOVE CALCULATIONS (SUBTOTAL)</b>				=	\$1,000.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date [37 CFR 1.492(f)].				+	
<b>TOTAL NATIONAL FEE</b>				=	\$1,000.00
Fee for recording the enclosed assignment [37 CFR 1.21(h)]. The assignment must be accompanied by an appropriate cover sheet [37 CFR 3.28, 3.31]. \$40.00 per property.				+	
<b>TOTAL FEES ENCLOSED</b>				=	\$1,000.00
				Amount to be refunded:	
				Amount to be charged:	
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>13-2755</u> in the amount of <u>\$1,000.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to the Deposit Account No. <u>13-2755</u>. A duplicate copy of this sheet is enclosed.</p> <p><b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive [37 CFR 1.137(a) or (b)] must be filed and granted to restore the International Application to pending status.</b></p> <p>SEND ALL CORRESPONDENCE TO:</p> <p style="border: 1px solid black; padding: 2px; display: inline-block;">Customer No. 000210</p> <p>MERCK &amp; CO., INC. Patent Department, RY60-30 P.O. Box 2000 126 East Lincoln Avenue Rahway, New Jersey 07065-0970</p> <p>DATE: <u>September 21, 2005</u></p> <p>PHONE #: <u>(732) 594-0672</u></p>					
				<p><u>Baerbel R. Brown</u></p> <p>SIGNATURE</p> <p><u>BAERBEL R. BROWN</u></p> <p>NAME</p> <p><u>47,449</u></p> <p>REGISTRATION NUMBER</p>	

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Serial No. PCT/US2004/015051  
Case Docket No.: 21397P  
International Filing Date: 14 May 2004  
Priority Date: 19 May 2003  
Title: PROCESS FOR MAKING SPIROLACTONE  
COMPOUNDS

Inventors: RALPH P. VOLANTE, STEVEN A. WEISSMAN,  
TAKEHIKO IIDA, YUHEI YAMAMOTO, HIROKI SATO,  
KENJI MAEDA, NAOTAKA SAWADA, and TOSHIAKI MASE

EXPRESS MAIL CERTIFICATE

DATE OF DEPOSIT September 21, 2005

EXPRESS MAIL NO. EL989586561US

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING  
DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS  
EXPRESS MAIL "POST OFFICE TO ADDRESSEE" BEFORE  
5 P.M. ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO  
COMMISSIONER OF PATENTS AND TRADEMARKS, BOX PCT,  
WASHINGTON, D.C. 20231.

MAILED BY Christine Cuffe DATE September 21, 2005